Role of the Laboratory Professional - New Opportunities

Jay M. McDonald, M.D.*
Richard C. Friedberg, M.D., Ph.D.,
Stephen A. Moser, Ph.D.
John A. Smith, M.D., Ph.D.
Department of Pathology
The University of Alabama at Birmingham
Birmingham, Alabama

***Presenting Author**

Abstract: New service opportunities for professionals in laboratory medicine parallel the new research opportunities in laboratory medicine health services research. Clinical laboratorians must extend both their clinical and research agendas beyond the confines of the clinical laboratory, forming multidisciplinary teams to address the key issues that add value to the health care delivery system. A new focus for laboratorians on cost-effectiveness and outcomes assessment is a vital component of the new research agenda. For example, test evaluations performed properly and comprehensively are a form of outcomes or effectiveness research. A rapidly growing Laboratory Medicine Health Services Research Program at the University of Alabama at Birmingham is an example of a program focused on these important issues. Using a truly multidisciplinary approach focused on hypothesis-driven research, this program has achieved extramural funding from multiple sources. This success emphasizes the excellent new opportunities available for investigators in laboratory medicine health services research.

The instability of the current health care system and the ongoing revolution in health care delivery has created new opportunities for laboratory medicine physicians and scientists. Many of these opportunities exist in the service environment. However, new opportunities in service activities translate directly into new investigative opportunities. Many of these are focused on the assessment of cost-effectiveness and outcomes, which underlie essentially all strategic decisions in the new health care environment. The professionals in laboratory medicine are in an ideal position to take advantage of this paradigm shift. Three key components of the health care delivery system are patients, providers and payers. Traditionally the laboratory medicine profession has rendered services primarily to health care providers (physicians who order tests) and have generally avoided the other elements, the patients and providers. The successful implementation of new service programs in laboratory medicine must focus on adding value to all three axes, not just the providers.

New service opportunities for clinical laboratory consultants (physicians and scientists) overlap with new research opportunities. Seven of these are listed in Table 1. Discussion of each of these is presented more extensively in the original article by McDonald and Smith.[1] However, it is important to stress that laboratory medicine consultants must add value to the health care system and the value added must be proven by health services research.

Service: Valued Added and Medical Relevance

1. Management of point of care testing: at any location
2. Information systems: laboratory and health care system wide
3. Consultants - clinical care
4. Resource managers: for laboratories and broadly in health care systems
5. Utilization management
6. Quality assurance
7. Technology assessment and implementation

Table 1. Expanded Service Opportunities for Laboratory Medicine Consultants [1].
([1]Adapted from Reference 1)

- Effectiveness
- Efficiency
- Appropriateness
- Technical Assessment of New Analyses

Table 2. Components of Laboratory Medicine Health Services Research.

Laboratory medicine consultants are equipped to be consultants in the management of point of care testing, no matter where and by whom it is done. Laboratory medicine consultants are experts in information systems as they apply to laboratories. The challenge now is to extend this expertise beyond the laboratory to the entire health care delivery system. Of course professionals in laboratory medicine are clinical consultants) but health services research has not been performed to prove their value, especially in the all-important primary care setting. Although laboratory professionals manage resources in the laboratory, they must be prepared to do so as consultants beyond the laboratory. Utilization management can be expressed in many ways in health care, including preparation, implementation and management of health care guidelines. The roles for laboratory medicine specialists in quality assurance and technology assessment and implementation are well defined in the laboratory. The new challenge is to use this expertise in areas outside the laboratory.

The laboratory is clearly an important focus for cost-effectiveness research. Approximately $100 billion is spent annually on laboratory testing with little, if any, prior cost-benefit analysis.[2] Utilization is non-standardized, however, and geographic variation in utilization has been well documented.[3] Since expenses are encapsulated, they are relatively easy to measure, at least in the aggregate. Finally,

laboratory testing is in a unique position in the health care system affecting essentially all levels of the health care system, from the home to the hospital.

Laboratory medicine health services research is a general term that encompasses clinical investigation focused on the impact of laboratory medicine practice on the quality and cost effectiveness of patient care. It includes, at a minimum, the components shown in Table 2. Effectiveness research as used here is synonymous with the more commonly used term, outcomes research. Effectiveness research focuses on developing and refining methods to identify high quality, cost-effective health care.[4] It includes evaluation of technologies and practice methodologies. Efficiency is the quality of output divided by the consumption of resources (cost) and is clearly a vital component of laboratory medicine research. Appropriateness defines the best use of medical technology in practice and must be highly focused on specific problems to be successful. These are all important components of the assessment of new technology, and are clearly the purview of laboratory medicine professionals. But like the service opportunities listed in Table 1, these research activities must be broadly defined to include traditionally extra-laboratory issues and must be actively and creatively pursued by laboratory professionals.

Test evaluations, properly performed, are one form of laboratory medicine health services research. Some general, rather obvious, principles that must be evaluated in any comprehensive test evaluation include patient outcomes and cost-effectiveness. A comprehensive cost analysis is vital and must include a breakdown into direct, variable, and fixed costs, since not all costs will be equally affected by the inclusion or omission of a procedure. Effectiveness or outcomes analysis involves assessment of many potential endpoints, a fact often overlooked by new investigators in the field. Some of these include such things as patient satisfaction, patient time in office, frequency of follow-up visits, and time away from work. Test evaluations must also develop criteria for appropriate utilization and consider whether newer methods should replace older methods or be added to the testing menu.

The keys to success in performing laboratory medicine health services research include these three principles: (1) the laboratorian must get out of the laboratory and into other administrative and clinical arenas of the health care system; (2) the laboratorian must lead or participate in multidisciplinary teams) all outcomes investigations are, by definition, multidisciplinary; and (3) all investigations must be hypothesis-driven. Omission of the last item is the most frequent and fatal error. If an hypothesis is not tested, the activity is not research, and conclusions cannot be extrapolated into future endeavors. Many additional key variables must be assessed when performing laboratory medicine health services research. As shown in Table 3, the impact of the provider, the service provided, analysis location, and the patient environment or location are all potential variables that may affect an outcome) and can, and should, influence the design of the research protocol. A separate area of research in laboratory medicine worth emphasizing is information management.[5,6] Information systems expertise is needed throughout the health care system in both service and research. For example, extraordinary opportunities exist in

Provider:	Self, paramedical practitioner, primary care physician, specialist physician
Service:	Laboratory analyses, quality assurance, utilization management, information system changes, analysis of aggregate or individual patient data
Location:	Home, hospice, nursing home, pharmacy, office, clinic, hospital

Table 3. Important Variables that Affect Outcomes in Laboratory Medicine Health Services Research

identifying appropriate uses for aggregated patient care data in assessing the quality and cost-effectiveness of health care.

Many groups, public and private, fund laboratory medicine health services research. The breadth of funding opportunities is, in many ways, more expansive than for basic research. Most importantly, the funding opportunities are increasing) not decreasing. Some of the agencies or groups that fund laboratory medicine health services research are shown in Table IV. The Agency for Health care Policy and Research is a government agency focused on cost-effective health care delivery. It funds the development of health care guidelines and protocols and funds individual and patient outcomes research team (PORT) grants. The Centers for Disease Control and Prevention (CDC) funds various kinds of contracts, especially those focused on the impact of laboratory quality. The National Library of Medicine funds programs focused on information systems in health care delivery; Dr. Donald Lindberg, Director of the National Library of Medicine, is both a pathologist and a pioneer in this field. The Veterans Affairs research program has some targeted programs, as do selective branches of the NIH (e.g., the National Institute of Nursing). Some private foundations, such as those listed in Table 4, have special interest in outcomes research and cost-effective health care delivery.

Industry must not be forgotten. Various product lines within the industrial sector are involved in cost-effective health care delivery. The funding of extramural research programs by managed care providers is vital, but it is new behavior for them. Hospitals also have renewed interest, given their conversion from revenue centers to cost-centers. Other Federal agencies such as the National Institute of Standard and Technology (NIST) has a health care information systems program through which the University of Alabama at Birmingham (UAB) Laboratory Medicine Health Services Research Program is being partially funded. Unfortunately, NIST is a branch of the Department of Commerce which is currently under extreme political pressure. Thus, the fate of this program is unknown. Finally, there are other Advanced Technology Programs funded by the government which can link industry to academia and which may be sources of funding, especially if new technology is being assessed.

The multidisciplinary Laboratory Medicine Health Services Research Program at UAB has multiple components as shown in Figure 1. The core programs include

1. Agency for Health care Policy and Research
2. Centers for Disease Control and Prevention
3. National Library of Medicine
4. Department of Veterans Affairs (VA)
5. NIH - e.g., National Institute of Nursing
6. Private Foundations - The Whitaker; Robert Wood Johnson
7. Industry - Varied product lines (insurance, reagents, equipment, HMOs and other provider groups
8. Hospitals
9. National Institute of Standards and Technologist (NIST)
10. Other Federal Advanced Technology Programs (ATP)

Table 4. Funding Opportunities for Laboratory Medicine Health Services Research.

outcomes or effectiveness research, clinical research support, product evaluation, education and informatics. This program supports developmental research in laboratory medicine and interfaces with numerous medical center outcomes-focused research programs. In addition, the program has laboratory-initiated projects in which laboratory medicine professionals are principal investigators. Examples of these projects include: (1) a subcontract with Cerner Corporation funded by NIST designed to automate laboratory practice guidelines on computers; (2) a project designed to develop a sentinel monitoring network of clinical laboratories focused on assessing quality of testing and the impact of CLIA '88 (funded by the CDC); and (3) another project recently funded by the CDC to develop an investigational consortium focused on the relationship between laboratory performance and patient outcomes. These independent research programs have all been funded within the last year and represent examples of the extraordinary opportunities available to support this kind of research.

In summary, new service opportunities in the emerging era of managed care and health care reform parallel new research opportunities in laboratory medicine health services research. Comprehensive test evaluations, which test an hypothesis and are properly performed, are forms of outcomes or effectiveness research. In addition, the interface between information systems and the health care delivery system represent unique opportunities for focused laboratory medicine-driven research programs. Finally, new funding opportunities are available for high quality laboratory medicine health services research.

In conclusion, this time of rapid change in the health care delivery system has created new and exciting service and research opportunities. Laboratory medicine

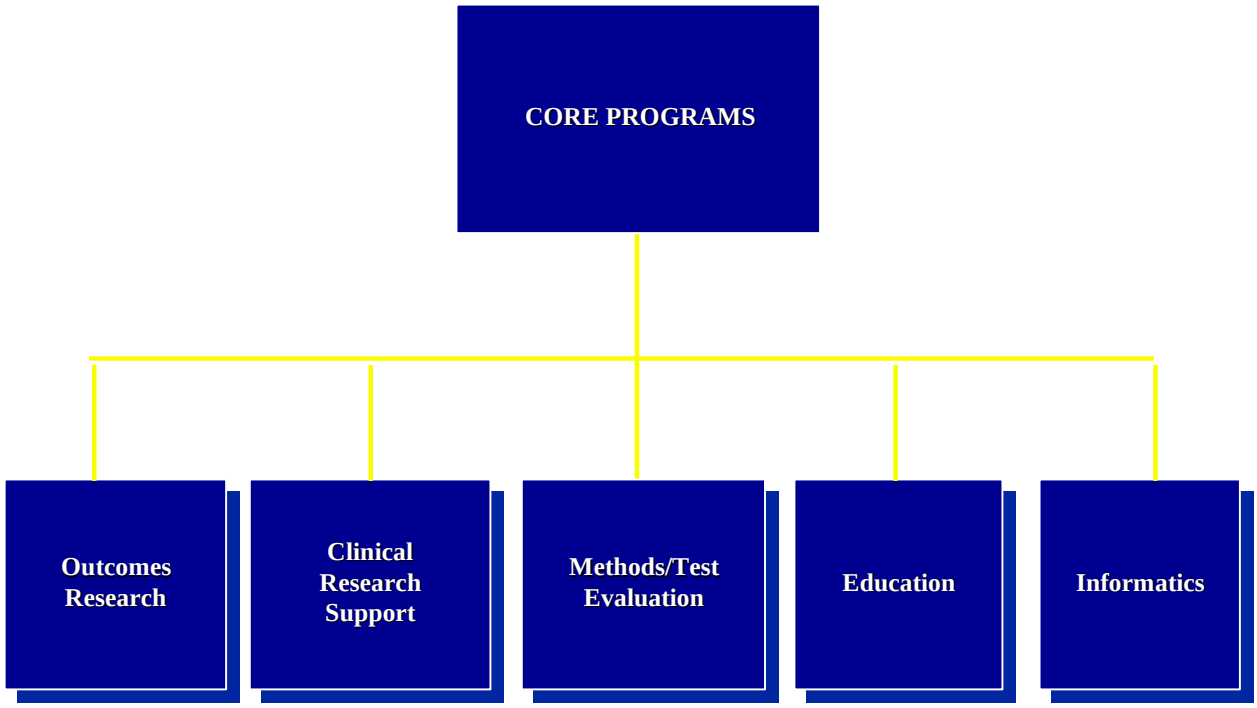

FIGURE 1

Figure 1. UAB Laboratory Medicine Health Services Research Program core activities.

professionals must take advantage of these opportunities, which will have broad impact on health care enterprise and allow laboratory medicine to be practiced at a new level with different boundaries than before.

Acknowledgments

The authors thank Marsha Moore and Tina Brown for their expert editorial assistance. This work is supported by a subcontract to UAB (JMM) from the National Institute of Standards & Technology grant to Cerner Corporation and a cooperative agreement with the Centers for Disease Control and Prevention (Assignment #U47/CCU411451, SAM).

References

1. McDonald JM, Smith JA. Value-added laboratory medicine in an era of managed care. *Clin Chem.* 1995;41:1256-1262.

2. Robinson A. Rationale for cost-effective laboratory medicine. *Clin Microbiol Rev.* 1994;7:185-199.

3. Welch WP, Miller ME, Welch HG, Fisher ES, Wennberg JE. Geographic variation in expenditures for physicians' services in the United States. *N Eng J Med.* 1993;328:621-627.

4. U.S. Congress, Office of Technology Assessment. Tools for effectiveness esearch. In: *Identifying health technologies that work:searching for evidence*. U.S. Government Printing Office, Washington, D.C. 1994:39-76.

5. Altshuler CH. Data utilization, not data acquisition, is the main problem. *Clin Chem*. 1994;40:1616-1620.

6. Korpman RA. Health care information systems: Patient-centered integration is the key. *Clin Lab Med*. 1991;11:203-220.